

JUL 29 1996

510(K) SUBMISSION FOR ULTRA CARE POWDER FREE HYPOALLERGENIC NS PATIENT EXAM GLOVE

ORIGINAL SUBMISSION DATE: JANUARY 9, 1996

SUPPLEMENTAL SUBMISSION DATE: MAY 17, 1996

REVISION DATE: JULY 26, 1996

510(K) SUMMARY

K960247

A. INFORMATION

1. SUBMITTER'S

NAME:

TILLOTSON HEALTHCARE CORPORATION

ADDRESS:

360 Route 101
Bedford, NH 03110 U.S.A.

TELEPHONE NUMBER:

(603) 472-6600

CONTACT PERSON:

Imogene Tibbetts

DATE SUMMARY PREPARED:

December 27, 1995

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME:

Ultra Care Powder Free Hypoallergenic
Non-Sterile Examination Glove

COMMON OR USUAL NAME:

Non-Sterile Powder Free
Patient Examination Glove Hypoallergenic

CLASSIFICATION NAME:

Patient Examination Glove3. PREDICATE DEVICE IDENTIFICATION
NAME, NUMBER1. Formula One Patient Exam Glove K891939
2. Sensi Shield Glove Kit, Inner Glove, K910383
(Hypoallergenic)

4. DESCRIPTION OF DEVICE

Patient examination gloves are made with an intact natural latex rubber film, which provides a barrier to body fluids and bloodborne pathogens, and between patient and examiner.

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR
CONDITIONS THAT THE DEVICE WILL ADDRESS

This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner.

Hypoallergenic patient examination gloves are suitable in situations where healthcare worker or patient allergic sensitivity may be a factor.

Powder free gloves are intended for use in situations where powder should not be used.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

- The proposed product is identical to the predicate product #1 in the following respects:

1. SPECIFICATIONS, ESPECIALLY WATER TIGHTNESS

The specifications for both gloves are identical with respect to water tightness and all physical parameters such as tensile and elongation. Results of testing demonstrate equivalence.

2. FORMULATION OF LATEX

- The formulation for the latex layer is identical in the proposed and predicate #1 gloves.

3. IT IS HYPOALLERGENIC

- Both Predicate #2 and Proposed product have passed a Modified Draize Repeat Insult Patch Test on human subjects, and have been found hypoallergenic.

- The proposed product is different from the predicate product #1 in the following respects:

1. FORMULATION/PROCESSING - METHOD FOR RENDERING GLOVE powder free.

The proposed product has an additional "slip coat" composed of a proprietary polyurethane coating, as a substitute for donning powder.

2. NO DONNING POWDER is added.

3. PROCESSING

The proposed product has two extra leach steps in its process.

4. LABELING: INTENDED USE

The labeling for both products will be substantially the same, including all required label statements.

The main differences from predicate #1 are the statements "Powder Free" and "Hypoallergenic".

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510(K) SUMMARY (continued)

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS
SPECIFICATION

PERFORMANCE STANDARDS

WATER TIGHTNESS

2. DISCUSSION OF CLINICAL TESTS
SPECIFICATIONSAFETY

RABBIT SKIN IRRITATION

GUINEA PIG SENSITIZATION

MODIFIED DRAIZE REPEAT
INSULT PATCH TEST

PREDICATE	PROPOSED
1. Formula One Patient Examination Glove	Ultra Care Powder Free Hypoallergenic
2. Sensi Shield Glove Kit Hypoallergenic Inner Glove	Patient Examination Glove
ASTM (#1)	ASTM
ASTM (#1 and #2)	ASTM
Passes (#1 and #2)	Passes
Passes (#1 and #2)	Passes
Passes (#2) on 200 human subjects	Passes on 300 human subjects

DESCRIPTION OF SUBJECTS

The Modified Draize Repeat Insult Patch Test, 300 human subjects were used.

DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED

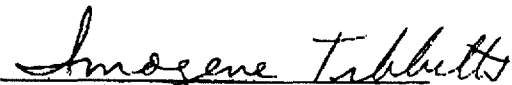
with specific reference to adverse effects and complications

Both the inside surface and the outside surface of Ultra Care Powder Free Hypoallergenic Latex Patient Examination Gloves were evaluated to determine their ability to sensitize the skin of normal volunteer subjects using occlusive repeated Insult patch study. About three hundred persons at three different locations completed the study. Under the conditions employed in this study, there was no evidence of sensitization

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE
SAFETY EFFECTIVENESS, AND PERFORMANCE = / > PREDICATE PRODUCT

The Ultra Care Powder Free Hypoallergenic Exam Glove has been compared to legally marketed devices in the 510(k). The data summaries indicate that the proposed product meets acceptable scores for the predicate products in physical, nonclinical and clinical tests.

Pursuant to 21 C.F.R. 807.87 (j), I, Imogene Tibbetts, Director of Medical and Scientific Support Services, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Director of Medical and Scientific Support Services for TILLOTSON HEALTHCARE CORPORATION, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Imogene Tibbetts

Director of Medical and Scientific Support Services